Remarks

The specification has been amended to correct typographical errors and to more properly recite designated trademarks.

The claims have been amended to more fully characterize the terms "AA" as arachidonic acid, "DHA" as docosahexaenoic acid, "PUFA" as polyunsaturated fatty acid, and "CB_1" as cannabinoid CB_1, support for which can be found in applicants' specification at page 17, lines 2-5; page 16, lines 24-30; and page 4, lines 15-19; respectively.

The claims have also been amended to more specifically characterize the polyunsaturated fatty acid as provided in the form of a triacylglycerol. Support for this amendment is found in Applicants' specification at page 17, lines 14-19 and 23-25.

Claims 1-29 remain in the application.

Technical matters

The specification has been objected to for reference to Similac Neosure ™ and Similac Special Care ™ without using all capital letters and an accompanied generic terminology. Responsive to this objection, the referenced marks have been amended in the manner suggested in the Office Action.

The Specification has also been objected to for several typographical errors. Responsive to this objection, the noted typographical errors have been amended in the manner suggested in the Office Action, with exception to the objection of the word "as" on page 23, line 4 of the specification. Applicants' respectfully submit that the latter is grammatically correct as written and should not be changed.

Claims 1, 2, and 3 have been objected to for reciting the terms "PUFA", "DHA", and "AA". Claim 12 has also been objected to for reciting the term "CB_1". Responsive thereto, the claims have been amended in each instance to further define the referenced term.
Claims 5, 6, 10, 11, 16, 17, 22, 23, 26, and 29, have been rejected under 35 USC 112, second paragraph, as indefinite for reciting the term "about" in the expression "from about 8 to about 15,832 mg." Applicants traverse this rejection, and submit that the term "about" is commonly

used and legally recognized in U.S. claims as a means to characterize the literal scope of a numeric range. Applicants respectfully submit that this particular rejection is improper and should, therefore, be withdrawn.

Claims 18-23 have been rejected under 35 USC 112, second paragraph, as indefinite for reciting the phrase "administering to at least some members of said population". Applicants traverse this rejection, and contend that one of ordinary skill in the art would know what it means to administer a composition to at least some members of a population, to thus reduce the incidence of obesity in that population. By administering the composition to an individual within a population, and thus reducing the incidence of obesity in that person, the incidence of obesity in the target population is likewise reduced. Accordingly, Applicants respectfully submit that this particular rejection is improper and should, therefore, be withdrawn.

Prior Art Rejections

A) 35 USC 102

Claims 1-29 have been rejected under 35 USC 102 as anticipated by Jandacek et al. (WO 02/00042). Applicants traverse this rejection as it would apply to the amended claims.

Jandacek et al. discloses compositions comprising satiety agents selected from the group consisting of long chain fatty acids and their non-glyceryl esters, hydrolyzable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach (see page 3, lines 27-33). Jandacek et al. exclude the use of triacylglycerols as satiety agents, noting that triacylglycerols are hydrolyzed in the small intestine rather than the stomach (see page 5, lines 4-6) and will thus have little effect on food intake (see page 5, lines 12-15).

It is respectfully submitted that Jandacek et al. fail to disclose all of the limitations of Applicants' broadest claims, as such claims are now limited to the use of long chain n-3 polyunsaturated fatty acids from triacylglycerols. As noted above, Jandacek et al. discloses *non-glyceryl esters* and *excludes* the use of the triacylglycerols to which all claims in the present application are now limited.

Applicants respectfully submit that this rejection is no longer proper as it would apply to amended claims 1-29. This rejection should, therefore, be withdrawn.

B) 35 USC 103

Claims 1-11 and 18-23 have been rejected under 35 USC 103(a) as unpatentable over Jandacek et al. (WO 02/00042). Applicants traverse this rejection as it would apply to the amended claims.

As noted above, Jandacek et al. disclose compositions comprising satiety agents selected from the group consisting of long chain fatty acids and their non-glyceryl esters, hydrolyzable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach (see page 3, lines 27-33). Jandacek et al. exclude the use of triacylglycerols as satiety agents, noting that triacylglycerols are hydrolyzed in the small intestine rather than the stomach (see page 5, lines 4-6) and will thus have little effect on food intake (see page 5, lines 12-15).

Applicants submit that Jandacek et al. fail to suggest the use any triacylglycerols, including the triacylglycerols of long chain n-3 polyunsaturated fatty acids to which all claims of the present invention are now limited. Although Jandacek et al. teach the use of long chain fatty acids and non-glyceryl esters as satiety agents, it fails to suggest the use of triacylglycerols.

Moreover, the Jandacek et al. reference actually teaches away from the present invention by stating that triacylglycerols will have little effect on food intake (see page 5, lines 12-15). Applicants have found, to the contrary, that certain dietary n-3 long chain polyunsaturated fatty acids (from triacylglycerols) do indeed affect food intake.

As summarized in the present application, Applicants conducted an animal study comparing rat milk formulas containing (1) no DHA or AA, or (2) 2.5% DHA and no AA, (3) no DHA and 2.5% AA, or (4) 2.5% DHA and 2.5% AA. The DHA oil in the study was DHASCO™ oil (Martek Biosciences Corp.) and the AA oil was ARASCO™ oil (Martek Biosciences Corp.), both of which are triacylglycerols of either DHA or AA fatty acids (see attached DHASCO, ARASCO internet publication at page 2, paragraph 2).

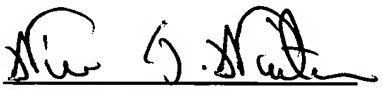
The results of the animal study included a showing that DHA oil (triacylglycerol of docosahexaenoic acid, 22:6 n-3) fed postnatally to rat pups from days 6-18 resulted in a 12% decrease in food consumption following food restriction on postnatal day 19. This particular finding is in contrast to the Jandacek et al. reference, which teaches that such triacylglycerols should have little effect on food intake.

In view of the amendments presented and the foregoing remarks, Applicants respectfully request withdrawal of this rejection as it would apply to the amended claims 1-29.

Conclusion

Applicants respectfully request reconsideration of this application, withdrawal of all pending objections and rejections, and allowance of claims 1-29.

Respectfully submitted,

By 

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NOVEL FOOD INFORMATION

DHASCO® AND ARASCO® AS SOURCES OF DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID IN INFANT FORMULAS

Health Canada has notified Martek Biosciences Corporation (Martek) that it has no objection to the sale of the products DHASCO® and **ARASCO®** for use as sources of docosahexaenoic acid (DHA) and arachidonic acid (ARA), respectively, in infant formulas (human milk substitutes). The Department conducted a comprehensive assessment of these oils, including toxicology, chemistry, microbiology, and nutrition.

BACKGROUND:

The following provides a summary of the Martek notification to Health Canada and contains no confidential business information.

1. Introduction

DHASCO® refers to a mixture of an **oil** extracted from the unicellular alga Crypthecodinium cohnii and high oleic sunflower **oil** (HOSO). The resulting mixed **oil** contains 40-45% of product weight as DHA. **ARASCO®** refers to a mixture of an **oil** extracted from the unicellular fungus Mortierella alpina and HOSO, and contains 38-44% ARA by weight. DHA and ARA are long-chain polyunsaturated fatty acids (LCPUFAs) that are naturally present in a variety of human foods, including breast milk. At present, infant formulas in Canada do not contain any DHA or ARA.

2. Development and Production of DHASCO® and ARASCO®

Methods for production of DHASCO® and **ARASCO®** from C. cohnii and M. alpina, respectively, have been published. Specific, proprietary production strains of C. cohnii and M. alpina and food grade materials are used in the production process. Oils from the biomasses are extracted and processed using procedures that are well established in the edible **oil** industry. The DHA and ARA contents of DHASCO® and **ARASCO®**, respectively, are standardized using HOSO. The oils undergo analytical and quality assurance testing and must meet defined specifications prior to release.

3. Product Information

DHASCO® and **ARASCO®** contain DHA and ARA, respectively, as triglycerides, with no detectable levels of eicosapentaenoic acid (EPA) or other LCPUFAs. Levels of EPA are consistently low in breast milk, and the addition of fish oils containing EPA to infant formulas has been associated with a decreased rate of growth. The major sterols present in DHASCO® and **ARASCO®** are consistent with those found in other human foods, such as fish and shellfish.

4. Dietary Exposure

DHASCO® and **ARASCO®** will be used as sources of DHA and ARA solely in infant formulas. Health Canada has not set out a specific level of use of DHASCO® and **ARASCO®** oils in infant formulas. Appropriate levels of addition will be established based on information provided by infant formula manufacturers in premarket notifications for products containing these oils.

5. Nutritional Quality

Evidence from a number of scientific studies demonstrates that the triglycerides containing DHA and ARA from DHASCO® and **ARASCO®** are absorbed by healthy infants in the same manner as other dietary triglycerides. Blood EPA levels also appear to be unaffected by consumption of formulas supplemented with DHASCO® and **ARASCO®** and there is no evident, significant retroconversion of DHA to EPA. Clinical studies show that infant formulas containing DHASCO® and **ARASCO®** support normal growth and development in healthy term and pre-term infants. Furthermore, a number of government and international scientific bodies have made recommendations with respect to the DHA and ARA contents of pre-term and term infant formulas. The Life Sciences Research Office, Federation of American Societies for Experimental Biology (2002), stated that infant formula for pre-term infants should contain no more than 0.35% and 0.6% of total fatty acids as DHA and ARA, respectively, and that, when these fatty acids are added, the ratio of ARA to DHA should be between 1.5 and 2.0. The Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, in their report Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids (2002), established an adequate intake of 0.5 g/day of n-3 polyunsaturated fatty acids for infants 0 to 6 months of age, which includes 0.04 g/day of DHA. No level of intake of DHA was specified for infants older than 6 months.

6. Safety

The strains of C. cohnii and M. alpina used in the production of DHASCO® and **ARASCO®** have not been derived through rDNA techniques. No toxicological, microbiological, or chemical concerns are associated with the supplementation of infant formulas with DHASCO® and **ARASCO®**.

Conclusion:

Health Canada's review of the information presented in support of the addition of DHASCO® and **ARASCO®** to infant formula does not raise concerns related to toxicological, microbiological, chemical, or nutritional safety. Health Canada is of the opinion that DHASCO® and **ARASCO®** are acceptable sources of DHA and ARA for infant formulas.

Health Canada's opinion pertains only to the use of DHASCO® and **ARASCO®** as sources of DHA and ARA in infant formula. No level of addition of DHASCO® and **ARASCO®** in formulas is specified. Pursuant to Division 25 of the Food and Drug Regulations, any manufacturer of infant formulas containing DHASCO® and/or **ARASCO®** would be required to submit to Health Canada evidence that the formulas are safe and nutritionally adequate to support acceptable growth and development in infants as part of the premarket notification for the formulas. Furthermore, any specific use of DHASCO® and **ARASCO®** in foods other than infant formulas would require a separate novel food notification pursuant to Division 28 of the Regulations.

For more information, please contact: food-aliment@hc-sc.gc.ca

Last Update : 2003/02/10 ▲ Important Notices